Remarks

Upon entry of the foregoing amendment, claims 15 and 24-57 are pending in the application. Applicants have canceled claims 1, 8, 13, 17-20, and 22 without prejudice or disclaimer. Applicants reserve the right to pursue the canceled subject matter in one or more continuing applications. Applicants have amended claims 36 and 43 by adding a functional limitation to the claims. Support for these amendments can be found in the specification in, for instance, Table 1E, pages 923-924. Thus, no new matter was added by way of these amendments.

The specification has been amended to correct a clerical error in the first paragraph of the application (claim to priority). The filing date of one of the Provisional Applications to which the present application claims priority was erroneously omitted in the preliminary amendment filed by Applicants on December 12, 2001. This filing date correctly appears on the filing receipt. Additionally, Applicants have removed several embedded hyperlinks present in the specification as requested by the Examiner (*see*, page 9 of Paper No. 0703). Hence, no new matter has been added by way of these amendments.

Election/ Restriction

Applicants would like to thank the Examiner for acknowledging the timely traversal of the restriction requirement. *See*, Paper No. 0703, page 2, "Election/Restriction" item. Applicants would also like to point out that, contrary to the Examiner's statement on page 2 of the pending Office Action, no amendments were introduced in original claims 1, 8, 13, 15, 17-20, and 22 in response to the Restriction Requirement (Paper No. 4). *See*, Paper No. 0703, page 2, "Election/Restriction" item.

Additionally, Applicants respectfully request clarification of the status of the rejoinder between Group III and Group V requested on page 11 in the response to Restriction Requirement filed March 25, 2003, as the Examiner has not given any ruling on said rejoinder request.

Priority

The Examiner has indicated that a priority date of September 12, 2001 (actual filing date of the present application) was given to the present application because, allegedly, "the provisional application upon which priority is claimed fails to provide

adequate support under 35 U.S.C. § 112 for claims 24-28, 30-34, 36-41, 43-48, 50-52, and 54-56, with respect to SEQ ID NO: 764 of this application." *See*, Paper No. 0703, paragraph bridging pages 2 and 3.

Applicants respectfully traverse and disagree.

Applicants assert that an earlier filing date of March 26, 1999 should be attributed to the present application. Clone HLYEU59 is described in U.S. Provisional Application No. 60/126,511, filed on March 26, 1999, in Table 1, page 56, row 10, as Gene No. 21, SEQ ID NO: 31 (nucleotide sequence) and SEQ ID NO: 81 (amino acid sequence). Applicants assert that SEQ ID NO: 31 of U.S. Provisional Application No. 60/126,511 is identical to SEQ ID NO: 260 of the present application. Additionally, Applicants assert that SEQ ID NO: 81 of U.S. Provisional Application No. 60/126,511 is identical to SEQ ID NO: 764 of the present application. A paper copy of the sequence listing was filed in conjunction with U.S. Provisional Application No. 60/126,511, filed March 26, 1999. However, no computer readable format of the sequence listing was filed, as this was not required at the time the provisional application was filed.

Applicants respectfully request that a priority date of March 26, 1999 be attributed to the present application.

Objections to the Specification

The Examiner objected to the disclosure "because it contains embedded hyperlinks and/or other form of browser-executable code." *See*, Paper No. 0703, page 9, "Specification Objections" item. More particularly, the Examiner pointed to "a) page 17, line 13; b) page 30, line 4; c) page 1906, line 24". *See*, Paper No. 0703, page 9, "Specification Objections" item.

Applicants have hereby amended the specification to remove the embedded hyperlinks a) and b) indicated by the Examiner. However, no embedded hyperlink could be found on page 1906 of the present application. Applicants have scanned the remainder of the specification and are not aware of any other embedded hyperlinks. Should Applicants find any additional embedded hyperlinks, those will be removed accordingly.

Claim objections

Claims 30-35, 43-49, and 54-57 are objected to "due to the claims not further limiting the subject matter of claims 24-29, 36-42, and 50-53, respectively." *See*, Paper

No. 0703, page 9, first paragraph. More particularly, the Examiner states that "the requirements of for example claims 30-35 are the literal translation of the limitations numerically and succinctly described in claims 24-29." *See*, Paper No. 0703, page 9, first paragraph.

Applicants respectfully traverse and disagree.

Preliminarily, Applicants respectfully submit that claims 24 and 30, 36 and 43, and 50 and 54 are independent claims. Therefore it is unclear why the Examiner asserts that claims 30, 43, and 54 must further limit the subject matters of claims 24, 36, and 50, respectively. Applicants further note that they are entitled to claim the invention using multiple claims, so long as the claim set as a whole clearly defines the subject matter of the invention. *See,* M.P.E.P. §2173.05(n). Furthermore, section 706.03(k) of the MPEP states:

> Inasmuch as a patent is supposed to be limited to only one invention or, at most, several closely related indivisible inventions, limiting an application to a single claim, or a single claim to each of the related inventions might appear to be logical as well as convenient. However, court decisions have confirmed applicant's right to restate (i.e., by plural claiming) the invention in a reasonable number of ways. Indeed, a mere difference in scope between claims has been held to be enough.

Applicants further note that it is routine and widely accepted in biotechnology patent practice to claim isolated proteins by an explicit recitation of the amino acid sequences as well as those isolated from a corresponding deposited clone. Thus, Applicants respectfully request that objection to claims 30-35, 43-49, and 54-57 be reconsidered and withdrawn.

Claim Rejection under 35 U.S.C. §101/112 first paragraph

The Examiner has rejected claims 24-57 under 35 U.S.C. § 101 because the invention is allegedly not supported by a credible, substantial, and specific, or well-established utility. *See,* Paper No. 0703, page 4, second paragraph. More particularly, the asserted utilities are allegedly not specific because "the disclosed uses of these compositions are not specific and are generally applicable to any predicted polypeptide sequence that was derived from computational analyses of the cDNA sequence." *See*, Paper No. 0703, page 4, third paragraph.

Applicants respectfully disagree and traverse.

Applicants submit that "an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101." M.P.E.P. § 2107.02(III)(A) at 2100-39; *see also, In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974). "Where an applicant has specifically asserted that an invention has a particular utility, the assertion cannot simply dismissed as 'wrong.'" M.P.E.P. § 2107 (III) B at 2100-40. "Office personnel should not begin by questioning the truth of the statement of utility. Instead, any inquiry must start by asking if there is any reason to question the truth of the statement of utility. This can be done by simply evaluating the logic of the statements made." *See*, M.P.E.P. § 2107.02 at 2100-39. Further, the PTO must accept the manner of making and using an invention disclosed in a specification "unless there is a reason for one of skill in the art to question the objective truth of the statement of utility or its scope." *In re Langer*, 183 U.S.P.Q. at 297; *see also, In re Marzocchi*, 58 C.C.P.A. 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) and *Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1098-99 (Jan. 5, 2001). Indeed, the Federal Circuit has characterized the standard for utility by indicating:

> The threshold of utility is not high: An invention is "useful" under section 101 if it is capable of providing some identifiable benefit. *See Brenner v. Manson*, 383 U.S. 519, 534 (1996); *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) ("To violate § 101 the claimed device must be totally incapable of achieving a useful result"); *Fuller v. Berger*, 120 F. 247, 275 (7th Cir. 1903) (the test for utility is whether the invention "is capable of serving any beneficial end").

Juicy Whip, Inc. v. Orange Bang Inc., 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999). Accordingly, the burden is on the Examiner to establish why it is more likely than not that one of ordinary skill in the art would doubt (*i.e.*, "question") the truth of the statement of utility. *See*, M.P.E.P. § 2107 at 2100-30; *In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995); and, *In re Cortright*, 49 U.S.P.Q.2d 1464, 1466 (Fed. Cir. 1999). The Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *See, id.* Such a *prima facie* showing must contain (1) an explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not specific, substantial, and credible; (2) support for factual findings relied upon in reaching this conclusion; and (3) an evaluation of all relevant evidence of record, including utilities taught in the closest prior art. *See, id.* Moreover, if applicants have presented reasoning used in asserting a

utility, the Examiner must present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the Applicants' assertion of utility. *See, id.* For the reasons set forth below, the Examiner has not met the burden that is necessary to establish and maintain a rejection for lack of utility under 35 U.S.C. § 101.

The Examiner further asserts "[t]he asserted specific utilities are based upon homology/identity to experimentally known sequences after translating the cDNA. It is noted that applicant(s) have listed a sequence which is known in the prior art and which has a high percentage sequence similarity to a claimed sequence." *See*, Paper No. 0703, page 4, fifth paragraph. Applicants respectfully traverse and disagree.

Applicants assert that specific, substantial, and credible utilities are disclosed in the specification for Gene No. 250 of the invention. Applicants note that the present claimed invention is primarily expressed in the spleen of humans afflicted with chronic lymphocytic leukemia (*see,* Table 1B, page 239 and Table 4, page 1884 of the specification (emphasis added)). In addition, Applicants disclose that the polypeptide of the claimed invention (SEQ ID NO: 764) activates transcription through the AP1 response element in immune cells, such as T-cells (*see,* specification, Table 1E, pages 923-924). Therefore, not only is the claimed invention useful for the diagnosis of a specific cancer, specifically chronic lymphocytic leukemia, but a specific *in vitro* biological activity is also provided.

Furthermore, contrary to the Examiner's statement, the asserted utilities are not based on homology to experimentally known sequences. As shown in Table 1E (*see*, above), the asserted utilities are based on experimental results, and a biological activity is shown for the polypeptides of the invention. Therefore, Applicants respectfully submit that the rejection of pending claims 24-57 under 35 U.S.C. § 101 is based on incorrect assumptions from the Examiner.

The Examiner further states that "it is unpredictable if the cDNA that encodes SEQ ID NO: 764 will successfully encode a functional protein in that it is not indicated to be a full-length open reading frame." *See*, Paper No. 0703, page 5, second paragraph. Additionally, the Examiner asserts "no actual protein with a defined functionality or biological activity is disclosed". *See*, Paper No. 0703, page 5, second paragraph. Applicants respectfully traverse and disagree.

Applicants respectfully point out to the specification, where Table 1A describes the "5' NT [nucleotide] of Start Codon" (column 9) and the "Last AA of ORF" (column 15), hereby describing the open reading frame corresponding to Gene No. 250 and encoding the HLYEU59 polypeptide of amino acid sequence SEQ ID NO: 764. *See*, Table 1A, page 61. Additionally, Table 1E provides information related to biological activities and preferred indications for polynucleotides and polypeptides of the invention (including antibodies, agonists, and/or antagonists thereof). The manner in which the described assays are performed is also disclosed. *See*, specification, paragraphs [53]-[55], pages 26-27. Applicants assert that the polypeptide of the claimed invention (SEQ ID NO: 764) activated transcription through the AP1 response element in immune cells, such as T-cells (*see,* Table 1E, pages 923-924). Therefore, contrary to the Examiner's comments, the specification provides the coding region of Gene No. 250, the corresponding polypeptide sequence, and a biological activity associated with this gene.

Additionally, the Examiner contends that the specification lacks specific utility because it includes "a further laundry list of diseases or disorders that are within the indications". *See*, Paper 0703, page 6, first full paragraph.

Contrary to the Examiner's contention, the disclosure of several uses for the claimed invention does not negate the specificity of any one of those uses. Indeed, the M.P.E.P. at § 2107.02 states "[i]t is common and sensible for an applicant to identify several specific utilities for an invention . . .". Further, "[i]f applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established." *Id. See also, In re Malachowski*, 189 U.S.P.Q. 432 (C.C.P.A. 1976); *Hoffman v. Klaus*, 9 U.S.P.Q.2d 1657 (Bd. Pat. App. & Inter. 1988). Therefore, the Examiner's assertion is improper and immaterial in the present case.

The Examiner further asserts that the invention allegedly is not supported by a substantial utility because "the protein is not experimentally characterized in any fashion, but partially characterized by predictions based on homology analyses to public database entries." *See*, Paper No. 0703, page 7, first paragraph. Additionally, the Examiner states that "[t]he research contemplated by applicant(s) to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a 'real world' context or

use." *See*, Paper No. 0703, page 7, first paragraph. Applicants respectfully traverse and disagree.

For the reasons stated above, Applicants respectfully assert that the claimed invention is supported by a substantial utility. Applicants have asserted that the claimed polypeptides are useful, for example, in the diagnosis (*i.e.*, as a diagnostic marker) of chronic lymphocytic leukemia. *See, supra.* As stated above, and contrary to the Examiner's comments, this utility is not based on "homology analyses to public database entries," but on experimental results, which provided a biological activity for the claimed polypeptides of the invention. As shown in column 4 of Table 1E (pages 923-924 of the specification), the polypeptide of the invention was shown to activate transcription through AP1 response element in immune cells (such as T cells). Such results provide an indication that the polypeptide of the invention is able to modulate cell growth (*see*, specification, Table 1E, column 5, pages 923-924). Additionally, the clone of the invention is primarily expressed in the spleen of humans afflicted with chronic lymphocytic leukemia (*see,* Table 1B, page 239 and Table 4, page 1884 of the specification). Consequently, it is reasonable to predict that the claimed polypeptides are useful, for instance, in the diagnosis of chronic lymphocytic leukemia. Applicants respectfully point to the M.P.E.P., which states "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'substantial' utility." *See*, M.P.E.P. § 2107.01(I) at 2100-33 (emphasis added). Applicants assert that, first the disclosed uses of the polypeptides of the invention are not generally applicable to all proteins. Second, the use of the claimed polypeptides in the detection of a specific disease such as chronic lymphocytic leukemia is certainly a "real world", substantial use as defined in the M.P.E.P.

Furthermore, Applicants respectfully remind the Examiner that utility can exist for therapeutic inventions "despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition." M.P.E.P. § 2107(III) at 2100-27. "Usefulness in patent law . . . necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans." *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) (Emphasis added).

As for the Examiner's position that "a percentage sequence similarity of less than 100% is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar know polypeptide[.]"(*see*, Paper No. 0703, page 4, fifth paragraph), Applicants respectfully point out to the Notice of the Federal Register of January 5, 2001, Vol. 66, No. 4, which refused to "adopt a *per se* rule rejecting homology-based assertions of utility" because no "scientific evidence that homology-based assertions of utility are inherently unbelievable or involve implausible scientific principles" was provided. Therefore, Applicants submit that homology-based assertions of utilities are not *per se* implausible.

In view of the arguments presented above, Applicants respectfully submit that the utility asserted in the specification for the claimed polypeptides HLYEU59 is indeed, specific, substantial and/or well established. Applicants therefore request that the rejection of claims 24-57 under 35 U.S.C. § 101 be reconsidered and withdrawn.

Claims 24-57 are also rejected under 35 U.S.C. § 112, first paragraph. *See*, Paper 0703, page 7, second paragraph. Specifically, the Office Action asserts "since the claimed invention is not supported by a specific, substantial, and credible utility, or, alternatively, a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention." *See,* Paper No. 0703, page 7, second paragraph.

For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, the claimed invention is supported by a specific, substantial and credible asserted utility. The Examiner "should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. §101 rejection is proper." M.P.E.P. § 2107 (IV) at 2100-36. Therefore, because the claimed invention complies with the utility requirement of 35 U.S.C. § 101, the rejections under 35 U.S.C. § 112, first paragraph, based on the alleged lack of utility of the claimed invention, should be withdrawn. Accordingly, Applicants respectfully request that the rejection of claims 24-57 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

Claim Rejection under 35 U.S.C. § 112 first paragraph (written description)

A. The Examiner has rejected claims 50-57 under 35 U.S.C. § 112, first paragraph for alleged lack of written description. *See,* Paper No. 0703, page 7, fourth paragraph. More particularly, it is stated "claims 50-57 are directed to specific fragment peptides that are 'at least 30 contiguous amino acid residues' which are not supported by the specification. In addition, the specification lacks support for any specific fragment of SEQ ID NO: 764, or any other sequence." *See*, Paper No. 0703, page 7, fourth paragraph.

Applicants respectfully disagree and traverse.

Primarily, Applicants respectfully point to the specification, more particularly to paragraph [218], pages 1904-1905 which describes polypeptide fragments derived from a polypeptide of amino acid sequence SEQ ID NO: Y or encoded by the ATCC Deposit NO: Z and which are at least about 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 100, 110, 120, 130, 140, or 150 amino acids in length. As defined in the description of Table 1A, more particularly in paragraph [10] on page 13 of the specification, SEQ ID NO: Y represents a polypeptide where Y may be any of the polypeptide sequences disclosed in the sequence listing. Similarly, the ATCC Deposit NO: Z is defined as a sample of plasmid DNA containing a human cDNA of the invention deposited with the ATCC, as set forth in Table 1A. *See*, specification page 13, paragraph [13]. Furthermore, Applicants direct the Examiner's attention to paragraphs [206]-[231] at pages 1898-1909 of the specification, which are entirely devoted to the description of fragments of polynucleotide sequence SEQ ID NO:X (in the present case SEQ ID NO: 260), fragments of polypeptide sequence SEQ ID NO:Y (in the present case SEQ ID NO: 764), and fragments of the cDNA contained in the ATCC Deposit NO:Z, shown in column number 3 of Table 1A (in the present case the HLYEU54 ATCC Deposit NO:203957) and of the polypeptides it encodes. Therefore, contrary to the Examiner's statement, the specification as filed provides ample support for specific fragments of the polypeptide of the invention.

Accordingly, Applicants respectfully request that the rejection of claims 50-57 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

B. The Examiner has rejected claims 24-57 under 35 U.S.C. § 112, first paragraph for alleged lack of written description. *See,* Paper No. 0703, page 7, fifth

paragraph. More particularly, it is stated "the claims are directed to encompass proteins corresponding to sequences of 90% or 95% identity to the overall or portion of SEQ ID NO: 764. The specific 10% or 5% that are not identical to the elected sequence are represented by the claim are not supported by the specification." *See*, Paper No. 0703, page 8, first paragraph. The Examiner further states "[a]lthough the sequence itself distinguishes the structural features of the nucleic acid, sequences, beyond exact identity (be it in entirety or to contiguous fragments) of the elected SEQ ID NO: 764, are included but not disclosed as to written description." *See*, Paper No. 0703, page 8, first paragraph (emphasis added).

Applicants respectfully disagree.

Preliminarily, claims 36 and 43 have been amended. Support for the amendment may be found, for example, on pages 293-294, Table 1E of the specification.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); and M.P.E.P. § 2163.02. The Federal Circuit recently re-emphasized the well-settled principle of law that "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed,'" *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000). While the applicant must "blaze marks on trees," rather than "simply [provide] the public with a forest of trees," an Applicant is not required to explicitly describe each of the trees in the forest. *See Unocal*, 208 F.3d at 1000. The Court emphasized the importance of what the person of ordinary skill in the art would understand from reading the specification, rather than whether the specific embodiments had been explicitly described or exemplified. Indeed, as the court noted, "the issue is whether one of skill in the art could derive the claimed ranges from the patent's disclosure." *Unocal*, 208 F.3d at 1001 (emphasis added). This is contrary to the Examiner's contention that sequences must be specifically enumerated in order to meet the written description requirement.

In an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting a *prima facie* case of unpatentability. This burden is only discharged if the Examiner can present evidence or reasons why one skilled

in the art would not reasonably conclude that Applicants possessed the subject matter as of the priority date of the present application. *See, In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q.2d 90, 96 (C.C.P.A. 1976); and M.P.E.P. § 2163.04. In the instant case, Applicants respectfully submit that the Examiner has not met this burden.

Applicants respectfully disagree with the Examiner and submit that one skilled in the art would reasonably conclude that Applicants had possession of the polypeptides encompassed by the rejected claims in the present application as filed. Applicants further submit that the Examiner has underestimated both the teaching of the present application and the level of skill in the art on the priority date of the present application.

Applicants submit that the specification does, indeed, provide adequate written description to enable one of skill in the art to make useful predictions as to the identities of the claimed polypeptides. Specifically, the specification provides ample disclosure of the characteristics of the HLYEU59 polypeptides and provides a detailed analysis of the methods needed to obtain, for instance, polypeptides exhibiting 90% or 95% homology with SEQ ID NO: 764 having transcriptional activation activity in immune cells. *See*, for instance, specification, at paragraphs [169]-[180], pages 1885-1890, and Table 1E on pages 923-924. Accordingly, one skilled in the art, enlightened by teachings of the present application (particularly, for example, the sequences associated with the HLYEU59 clone), could readily envision countless polypeptide sequences that comprise the specified polypeptides. For example, the skilled artisan could clearly envision each of the polypeptides that are 95% identical to the polypeptide of SEQ ID NO: 764 as a polypeptide with 1, 2 or up to 5 amino acid substitutions along its length. Indeed, nothing more than a basic knowledge of the genetic code and what is described in the specification would be required for the skilled artisan to identify every single one of the polypeptides that are 90% or 95% identical to the amino acid sequence of SEQ ID NO: 764. Clearly, such knowledge is well within what is expected of the skilled artisan as admitted by the Examiner, as quoted above and as stated on the record at page 8, first paragraph of Paper No. 0703.

Furthermore, the Examiner's argument that "[e]ach variation of the 5% or 10% non-identical, results in a new and independent sequence that does not reliably result in similar or identical biological activities as result for example from altered folding patterns[.]" (*see*, Paper No. 0703, page 8, first paragraph) is now overcome in view of the amendments made to claims 36 and 43.

The Examiner further alleges "[t]hus the instant claims are directed to encompass peptide sequences that correspond to sequences from other species, mutated fragment sequences, allelic variants, splice variants, and so forth. None of these additional sequences meet the written description provision of 35 USC 112, first paragraph." *See*, Paper No. 0703, page 8, first paragraph. Applicants respectfully traverse and disagree.

Applicants respectfully indicate that the claimed invention is specifically directed to human secreted proteins (*see*, Abstract), and in particular, polypeptides corresponding to the selected clone of the invention, HLYEU59. As for other sequences (mutated fragment sequences, allelic variants sequences, or splice variants), Applicants respectfully submit that, for the reasons stated above, and because Applicants have provided the core structural feature of the polypeptides of the inventions, namely SEQ ID NO: 764 and a defining biological activity, the disclosure provides adequate written description support, particularly at pages 1885-1909, paragraphs [169]-[231], and Table 1E on pages 923-924 of the specification.

Finally, Applicants note that it is unclear how the Examiner's statement on page 7, last paragraph of Paper No. 0703, relates to the written description requirements. As discussed above, Applicants have ascertained a biological activity associated with the polypeptides of the invention and have adequately described the species encompassed within the scope of the claims, as recognized by the Examiner, therefore, Applicants submit that the pending claims fully meet the written description requirements of 35 U.S.C. § 112, first paragraph, and respectfully request that the Examiner's rejection of claims 24-57 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

B. The Examiner has rejected claims 30-35, 43-49, and 54-57 under 35 U.S.C. § 112, first paragraph for alleged lack of written description. *See,* Paper No. 0703, page 8, third paragraph. More particularly, it is stated "[t]he specification provides insufficient written description to support the biological deposits of the claims." *See*, Paper No. 0703, page 8, third paragraph.

Applicants respectfully traverse and disagree.

Applicants respectfully point to the specification, particularly to paragraph [67] at page 32, where it is stated "The ATCC deposits were made pursuant to the terms of the Budapest Treaty on the international recognition of the deposit of microorganisms for the

purposes of patent procedure." Furthermore, Applicants provide herewith a statement complying with the requirements of 37 C.F.R. § 1.808.

The undersigned attorney of record hereby states:

1. ATCC Deposit No. 203957 containing human cDNA encoding the Secreted Protein HLYEU59, clone HLYEU59 was deposited with the American Type Culture Collection (ATCC), now located at 10801 University Boulevard, Manassas, VA 20110-2209, U.S.A. on April 26, 1999, in compliance with the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

2. I hereby assure the United States Patent and Trademark Office and the public that (a) all restrictions on the availability to the public of a sample of the above-mentioned deposited plasmid will be irrevocably removed upon issuance of a United States patent of which the plasmid(s) is a subject; (b) the above-mentioned deposited plasmids will be maintained for a period of at least five years after the most recent request for the furnishing of a sample of the plasmid was received by the ATCC and, in any case for a period of at least 30 years after the date of deposit or for the enforceable life of such patent, whichever is longer; (c) should the above-mentioned deposited plasmid become non-viable or mutated or otherwise incapable of being furnished by the depository upon request due to the condition of the deposit, the plasmid will be replaced by the Applicants; and (d) access to the above-mentioned deposited plasmid will be available to the Commissioner during the pendency of the patent application or to one determined by the Commissioner to be entitled to such plasmid under 37 C.F.R. § 1.14 and 35 U.S.C. § 122.

Applicants assert that the above statement is sufficient to overcome the Examiner's rejection and respectfully request that the rejection of claims 30-35, 43-49, and 54-57 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

Conclusion

Applicants respectfully request the amendments and remarks of the present response be entered and be made of record in the file history of the present application. In view of the foregoing amendments and remarks, Applicants believe they have fully addressed the Examiner and that this application is now in condition for examination. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Applicants believe that there are no fees due in connection with the filing of this paper. However, should a fee be due, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: December 10, 2003

Respectfully submitted,

By _____

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